Health ABC Manual for MR Imaging of the Knee

Version 1.2 December 11, 1998

KNEE MRI

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KNEE MRI

1.0 Introduction

1.1 Background and rationale

Despite the proven value of knee radiography in epidemiological studies of osteoarthritis (OA), radiography is fundamentally limited in a number of ways. Conventional radiographs provide detailed images of cortical and trabecular bone, but cannot directly visualize the articular cartilage or other noncalcified structures in the knee. Osseous findings are common in OA, but tend to arise late in the disease process and may be only secondary consequences of changes in other structures, such as the cartilage, menisci and intra-articular ligaments. Also, radiography is a projectional technique that casts two-dimensional (2D) shadows of the 3D anatomy onto flat sheets of film. This results in morphological distortion, magnification and superimposition of overlying structures.

MRI offers a number of advantages over radiography for imaging knee OA. MRI has a tomographic viewing perspective, and thus provides cross-sectional images of the anatomy, free of projectional distortion, magnification, or superimposition. This allows osteophytes and other abnormalities to be delineated in regions that might otherwise be obscured with conventional radiography. Moreover, MRI is uniquely able to directly visualize all components of the joint, including the articular cartilage, menisci, intra-articular ligaments, synovium, capsular structures, bone contours and bone marrow. This allows the knee joint to be evaluated as a whole organ, and provides a much richer picture of the changes associated with osteoarthritis than is possible with other techniques.

1.2 Purpose of the Manual

The purpose of this manual is to standardize the imaging technique and administrative procedures related to the MRI component of the **Health ABC protocol** for evaluating participants with osteoarthritis of the knee. The manual describes the MRI technique to be used along with the procedures for documenting and shipping the MRI data to UCSF. The manual is designed for the principal investigator, the study coordinator and MRI technicians involved in this study.

The role of the Osteoporosis and Arthritis Research Group at UCSF will be to verify that all sequences in the protocol were included and that the pulse parameters used were in agreement with the protocol. The images will also be checked for adequate anatomical coverage, signal-to-noise ratio, and the presence of artifacts. If any problems

or deficiencies are detected, the Osteoporosis and Arthritis Research Group at UCSF will notify the MRI site and work with them towards a solution. Only rarely would this require repeat examination of a participant.

The Osteoporosis and Arthritis Research Group at UCSF will perform centralized analysis of the MRI data. Assessments will include semiquantitative scoring of articular cartilage, osteophytes, subarticular cysts, bone marrow edema and sclerosis, attrition and remodeling of osseous articular surfaces, the menisci, the cruciate and collateral ligaments, joint effusion, synovitis, intra-articular loose bodies, and synovial cysts and bursae about the knee.

1.3 General study design

Baseline MRI will be performed at the year 2 Health ABC examination on participants with significant knee symptoms and on controls without symptoms; follow-up MRI will be obtained at the year 7 examination. Participants will undergo bilateral knee imaging.

MRI will be performed using 1.5 Tesla whole body scanners with a circumferential extremity coil. Imaging sequences will include, a fast axial T2-weighted localizer (duration <1 min), a sagittal T2-weighted fast spin echo sequence with fat suppression, and a coronal T2-weighted fast spin echo sequence without fat suppression. The total time required for MRI, including participant set up, will be approximately 30 minutes.

1.4 Which participants will get MRI?

Participants with significant pain in either knee will undergo bilateral knee MRI. Significant knee pain will be defined first by the questions asked on the Pre-visit Screener for Knee X-ray (Appendix 1) and then by the following questions found on pages 34 and 35 of the Year 2 Clinic Visit Workbook:

Question 1: In the past 12 months, have you had any <u>pain</u>, <u>aching or stiffness</u> in your left/right knee on most days for at least a month?

Question 2: In the past 30 days, have you had any <u>pain, aching or stiffness</u> in your left/right knee on most days?

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Question 3: In the past 30 days, how much <u>pain</u> have you had in your left/right knee for each activity I will describe. How much pain have you had while...?

- a) Walking on a flat surface
- b) Going up or down stairs
- c) At night while in bed
- d) Standing upright
- e) Getting in or out of a chair
- f) Getting in or out of a car

A participant who answers "Yes" to Questions 1 or 2 for either knee, or who has moderate or worse pain in one or more activity of Question 3, will be eligible for a knee MRI examination. Those who answer "Yes" to Question 1 or 2 are also eligible for a knee radiograph.

These questions will be asked at the clinic visit and a bilateral knee MRI exam scheduled at that time.

In addition, a random sample of participants without significant knee pain (do not qualify for knee MRI based on any of the above questions) will be asked to undergo knee MRI. These subjects will be notified at the clinic visit and an MRI exam scheduled at that time. (See Appendix 5)

1.5 MRI evaluation

MR images will be analyzed with a semiquantitative whole-organ scoring method.

1.6 Training and certification of MRI technologists

Each MRI facility participating in Health ABC should designate a study coordinator who is responsible for assigning technicians to the study and assuring that the procedures described in this manual are followed.

Only designated and certified technicians should perform the examinations for Health ABC. Each technician and coordinator involved in the study will have a unique Health ABC ID number. It is preferred that no more than 2 or 3 technicians be assigned to Health ABC at each MRI facility.

A representative of the UCSF OARG will visit each site to review the study procedures with the study coordinator and MRI technicians. Technicians will be certified based on the review at OARG of the first five Health ABC participants scanned.

2.0 MRI Protocol

2.1 MRI contraindications

The following are standard contraindications for MRI. These should be assessed using the Health ABC form at the time of the enrollment into the MR study and participants excluded from the study as appropriate. Each facility may have additional assessments to identify exclusions.

Contraindication (assessment)

- Body weight in excess of about 250 lb (measured weight at clinic visit) Subjects with a large body circumference may not fit in the MRI bore. This weight is only an approximate cutoff. Many subjects who are over this weight, especially those who are tall, may undergo MRI depending on body shape, since it is the size of the bore rather than weight, per se, that is the limiting factor. If a participant is over 250 lbs, take a quick measurement of waist and hip circumference over clothing (tape should bring clothing into contact with skin). The circumference of the bore is 176 cm. (Actual bore circumferences may differ by center.) Anyone with a waist or hip circumference above 160 cm is unlikely to fit in the bore.
- * Cardiac pacemaker ("Do you have a heart pacemaker?")
- •* Aneurysm clips of any age ("Have you ever had surgery to repair an aneurysm?")
- •* Metallic fragments in the eyes ("Have you ever worked in a machine shop where small metal slivers may have entered your eye? Have you ever had an injury in which metal or metal fragments may have entered your eye?")
- •* Vascular clips <2 months old ("Have you had any surgery in the past 2 months?") MRI for these subjects can be scheduled at a later date that is past the 2 month exclusion window.)
- •* Cardiac valve prosthesis ("Have you <u>ever</u> had surgery to insert a valve into your heart?")
- •* Cochlear implants ("Have you had a hearing device surgically implanted in your ear?") This does not include a standard hearing aid which can be removed.
- Total knee replacement ("Have you had a total knee replacement in either knee?") MRI on the knee opposite the replaced one will be distorted.

- Claustrophobia ("Do you have claustrophobia?") For those who answer yes, determine if they are willing to attempt the test. True claustrophobia is relatively uncommon (2-3%). Participants with claustrophobia will know who they are, and these people will probably not be willing to attempt the test. Some may say they are uncomfortable in small spaces, but may tolerate MRI without difficulty. It is useful to make an attempt in persons who seem uncertain or who have mild concern. MRI information booklets or a picture of someone in the bore for a knee exam may be helpful in orienting the participant.
- * Denotes a safety-related contraindication. In general, "Don't know" and "Refused" for these questions should be considered a contraindication.

2.2 Participant Set up

Proper participant set up should ensure correct positioning of the knee and sufficient participant comfort to limit motion artifacts and minimize the likelihood of participant dropouts.

Positioning

Positioning of the knee in the magnet must be reproducible from visit to visit in order to allow accurate comparison of serially acquired images. The participant should be imaged supine with the leg in neutral position and the <u>patella pointing straight up</u> rather than in slight external rotation as is commonly the routine in clinical imaging protocols. External rotation is more difficult to reproduce on serial exams and complicates image interpretation in this study. Additionally, the knee must be well immobilized in the circumferential extremity coil with foam padding.

Participant comfort and prevention of motion artifacts

The comfortable installation of the participant at the beginning of the examination is critical to limiting motion artifacts. Care should be exercised in positioning the cushions and pads around the knee in the extremity coil to make the examination as comfortable as possible. Ear plugs or music through headphones should be included along with pillows, blankets and verbal reassurance.

2.3 Imaging parameters

See Section 3.2 on how to complete the MRI header.

All parameters for the Health ABC protocol should be pre-programmed into the MRI computer in order to limit the potential of human error. The total examination time including 10-minutes participant setup is approximately 30 minutes for both knees. **Bandwidth should be 16 kHz for all sequences**.

- 1. Axial T2-weighted fast spin echo (FSE) localizer including entire patella:
 - 2500 / 60 (TR msec / TE msec),
 - 20 cm field of view (FOV),
 - 4 mm / 1 mm (slice thickness / interslice gap),
 - 256 x 128 matrix,
 - frequency encoding anterior-posterior,
 - 16 echo train length (ETL),
 - 1 excitation (NEX).
 - [Imaging time = 30 sec].
- 2. Sagittal T2-weighted fast spin echo (FSE) including entire synovial cavity; localize the slices from sagittal to medial.
 - 4217/60,
 - 14 cm FOV.
 - 4 mm / 0.5 mm (about 20 slices),
 - 256 x 224 (or 256) matrix,
 - frequency encoding anterior-posterior,
 - 8 ETL.
 - 2 NEX,
 - No phase wrap (NP),
 - frequency-selective fat suppression.
 - [Imaging time = 4:13 or 4:30 min, depending on the size of the matrix].
- 3. Coronal T2-weighted FSE:
 - 3500/60,
 - 14 cm FOV.
 - 4 mm / 0.5 mm,
 - 256 x 256,
 - frequency encoding medial-lateral,
 - 8 ETL,
 - 2 NEX,
 - No Phase wrap (NP).
 - [Imaging time = 4:00 min].

• Coverage should include the entire femorotibial joint but not the patella as shown in Fig. 1.]

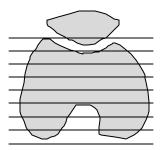


Figure 1. Coronal slice selection. Selected using axial localizer from Sequence 1 to cover entire femorotibial joint, but not the patella.

2.4 Examples of images

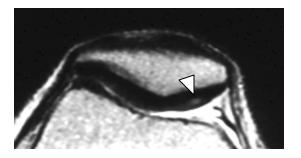


Figure 2: Axial T2-weighted fast SE image. These images will serve as localizers for other sequences but also for assessing cartilage, osteophytes and patellar subluxation. In this patient the patella shows a focus of increased signal intensity (arrowhead) indicative of chondromalacia in the cartilage over the medial facet.

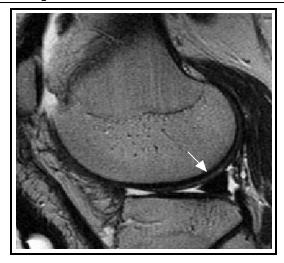


Figure 3: Sagittal T2-weighted Fast Spin-echo image. In contrast to synovial fluid, which shows high signal intensity with this technique, normal cartilage appears low in signal intensity. A focus of increased signal intensity (arrow) in the femoral cartilage over the posterior horn of a partially resected meniscus is indicative of chondromalacia.

2.5 Common mistakes or artifacts

Fat saturation failure or omission:

Frequency-selective fat saturation pulse must be used in the sagittal T2-weighted fast spin echo sequence. It eliminates chemical-shift artifacts along cartilage margins and is essential for detecting bone marrow edema. Fat saturation failure can occur over areas of irregularly shaped anatomy, such as the patella. Usually, this artifact does not extend to the patellar cartilage, but can interfere with assessment of patellar marrow edema. Accidental omission of the frequency-selective fat saturation pulse is a significant oversight.

Motion artifacts:

Participant motion artifacts can be minimized by positioning the participant comfortably using cushions and pads around the knee, and emphasizing the importance of lying still to the participant.

2.6 Filming protocol

Format

The three sequences should be filmed. Images should be printed with a 3×4 format (12 images per film) with the anatomy depicted from lateral to medial (sagittal) (fig. 4), posterior to anterior (coronal), and superior to inferior (axial). Images should be ordered from the left to the right and from the top to the bottom of the film. Sequences should be filmed on a separate sheet (i.e., two different sequences should not appear on the same sheet). The first image on the top left should be the localizer showing the slice selection. Sections at the periphery of the coverage that do not include any relevant anatomy need not to be filmed.

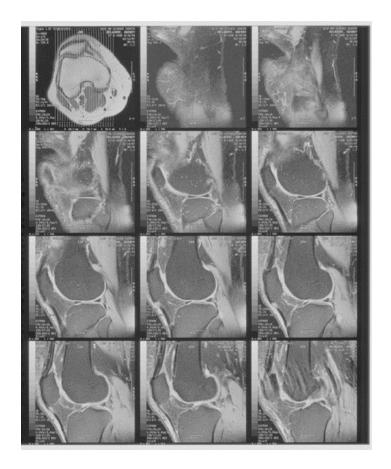


Figure 4: Proper film formatting of sagittal images. Images are printed 12 frames per film $(3 \times 4 \text{ format})$, with the localizer showing slice locations positioned in the upper left corner.

Magnification

Magnification should be the same from one examination to another for the same participant and should be documented on the MRI Logsheet (Appendix 3).

Windowing and leveling

Image window and level settings should be selected as in routine clinical practice to maximize discrimination of anatomy and pathology.

3.0 Data handling on site

3.1 Completing the MRI Logsheet

MRI Logsheets are provided to the clinical sites. Specific MRI information regarding the participant visit should be recorded onto this MRI Logsheet for each knee exam performed. Prior to shipping the data, a photocopy of each participant Logsheet must be made. The copy of the MRI Logsheet should be kept in the participant's clinic visit folder at the Health ABC clinic and be available for the follow-up visit. The original should be included in the package and sent to the OARG at UCSF. A separate Logsheet must be used for each participant and for each visit.

An example of the MRI Logsheet (Appendix 3) is enclosed in this manual.

All of the following fields MUST be completed in the Logsheet by the MRI site prior to forwarding the data to the HABC clinical center:

Page 1

- HABC Enrollment ID and Acrostic.
- Date of MRI exam using the date format (mm/dd/yy).
- Clinical site (check one)
- Completeness of participant's MRI packet.
- The date that the participants scan data and films are shipped to OARG (UCSF). Use format mm/dd/yy. (To be filled out by the HABC clinic.)
- HABC Staff ID of MRI coordinator checking packet completeness

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- Record examination number assigned by the MRI software for the right and left knees.
- Film magnification: none or 1.2.
- Internal Quality Assurance (QA) performed at time of exam
 - Sequences checked (check OK or not OK)
 - Important: Record sequential number of the DAT tape (or optical disk) used to record the exam. This number is the only link between a participant ID and the specific DAT tape (or optical disk) containing their data.
 - DAT tape (or optical disk) contents checked (check OK or not OK)
 - MRI exam and QA check performed by (HABC Staff ID).
- Comments: Note reasons for any "not OK" in QA check. Specify changes to the protocol, such as change in the frequency encoding axis.

3.2 Labeling the images

The following information should appear on:

- 1. the MRI header (so that it will appear on the printed film copy and DAT tape or optical disk),
- 2. the film copy jacket.
 - Clinic location and name (e.g. Memphis Baptist)?
 - "HABC" and participant enrollment ID (H __ _ _ _ _)
 - Participant name or acrostic
 - Date of MRI exam (mm/dd/yy)

The side (right or left) imaged should be indicated on:

the film copy by annotating the localizer scan, and the MRI header by entering "Right" or "Left" into the "Description" field. NOTE: Each knee has a different examination number.

Use one film jacket per participant.

Each participant's images should be stored on DAT tape or optical disk. We specify

4mm DDS 60, 1.3 GB capacity cassettes, NOT 4mm DDS90.

The Imation Product number is "DDS-60." Their Web site (http://www.imation.com/dsp/cmptblty/48_media.html) has a handy list of equivalent products from other manufacturers.

For example:

BASF 4 mm DG-60M Maxell HS-4/60 Memorex 32023022 Sony DG-60M TDK DC4-60 Verbatim DL60M

Each DAT can contain up to 5 examinations; each optical disk can contain up to 10 examinations. Follow the manufacturer's directions that come with the DAT tape or optical disk before applying the label(s).

Label the DAT tape (or optical disk) with the following information:

- Use the color-coded, prenumbered stick-on label provided by OARG (each site will have its own color). If this label is not available, use the DAT tape or optical disk manufacturer's label and assign a unique, sequential number to the label.
- Participant enrollment ID and exam date (mm/dd/yy) for each of the up to 5 examinations for DAT tape and up to 10 examinations for optical disk should be included on the tape or disk.

Each optical disk can have only two labels, which contain 10 patients' MRI images on each optical disk. The labels can not be put on the sides over regions where the metal cover of optical disk can slide. MRI center should read the instruction and figure of disk labeling carefully so as to label the disk properly. These labels can neither interfere with the operation of disk nor jam the computer drive.

3.3 On-site Quality Assurance (QA)

The MRI tech and the MRI coordinator for Health ABC at the site have the responsibility of ensuring that the quality of the shipment (image data and Logsheet) are checked BEFORE the package is sent to the clinical center for shipment to the OARG.

Each participant exam should be checked for:

- 1) Completeness:
 - a) All three sequences for each knee
 - b) Complete and accurate MRI Logsheet

2) Reproducible technique:

The data has been acquired using the correct MRI parameters in strict accordance to the OARG MRI protocol. In some cases, the exact recommended MRI parameters cannot be achieved for one reason or another, e.g., the TR or field of view may have to be increased slightly for an unusually large knee to achieve full anatomical coverage. It is important that any such deviations from protocol be documented and explained on the MRI Logsheet and implemented in all subsequent MRI visits.

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- 3) Image quality: Images should be checked at the time of the exam by the MRI tech for proper anatomic coverage, adequate signal-to-noise ratio and the absence of artifacts:
- a) Motion artifacts: Images that are degraded by participant motion artifacts should be repeated <u>once</u> following correction of any cause of participant discomfort or anxiety. Often verbal reassurance is sufficient to allay mild participant anxiety. However, severe claustrophobia may require that the participant be withdrawn from the study.
- b) Metallic artifacts in acquired scans: these images should be sent to OARG in the usual way, with the problem noted on the log. OARG will determine whether the images can be analyzed.
- c) Aliasing: The use of No Phase Wrap should avoid aliasing. Rarely, phase and frequency encoding directions must be swapped. This should be avoided, particularly on the coronal images, as the current frequency-encoding direction has been selected to minimize chemical-shift artifacts along femorotibial cartilage margins. It is important that any such deviations from the original protocol be documented and explained on the MRI Logsheet, and that the changes be replicated in all subsequent MRI visits.

3.4 Labeling Optical disks

Optical disks have to be labeled very carefully. <u>It is very important that the labels do</u> not obstruct the region of the disk where the metal cover of the disk slides.

To orient yourself, hold the optical disk so that the metal cover is at the top and the writing is right side up. If side A is facing you, the metal cover will slide to the right. Therefore, the label must be placed on the <u>left</u> side of the disk. On Maxell optical disks, this area is labeled "A." On Hewlett Packard disks, this is the area where it is <u>not</u> labeled "A."

If the B side is facing you, the metal cover slides to the left. Therefore, the label can only be placed on the <u>right</u> side. On Maxell disks, this area is labeled "B." On Hewlett Packard disks, this is the area where it is <u>not</u> labeled "B."

It is very easy to test whether you are putting the label in the right place. If you can move the metal cover without it passing over the label, you've got it right. Obviously, you should be careful not to touch the disk itself. Another suggestion might be to use only one brand of optical disk so you can always label in the same way and you will be less likely to make this mistake.

Please make sure that everyone at your institution who labels optical disks fully understands these instructions. The Field Center QC people (Joyce and Piera) are responsible for double checking that these labeling rules have been followed before sending the shipment on to the Reading Center. Any questions regarding labeling rules or shipments should be directed to Jing Li at (415)-502-2477.

3.5 Shipment to OARG at UCSF

A complete shipment consists of the following items:

- 1. Log sheets showing the information of participants whose scans are included in: 1) HABC enrollment ID #, 2) Acrostic #, 3) Date of MRI, 4) Field center, 5) Date of shipment, 6) MRI coordinator ID #, 7) Exam numbers, 8) Film magnification factor, 9) DAT tape/optical #, 10) MRI technician ID #.
- 2. Hard copy of the films (all 3 sequences for each knee scanned) with each participant in separate, labeled jackets;
- 3. DAT tapes or optical disks with the archived images for each participant labeled with HABC ENROLLMENT ID #, EXAM DATE, and SEQUENTIAL NUMBER of DAT TAPE/OPTICAL DISK of each participant on the tape or disk. The images

from no more than 5 participants should be on each tape, and no more than 10 on each optical disk.

These shipments should be sent at least every 2 weeks to the Reading Center.

It is the responsibility of the MRI Coordinator at each facility to ensure the completeness of each shipment before giving it to the Field Center to send to the Reading Center. This includes checking that all disks and tapes are labeled correctly and that for every participant log sheet there is a corresponding entry on a tape or optical label, and vice versa. All hard copies of scans (3 per knee) should be in a separate labeled jacket for each participant on the log sheet.

In addition, the QC person at each Field Center (Piera and Joyce) is responsible for checking the contents of each package before shipping. Again, this includes checking that all disks and tapes are labeled and that each participant on the log sheet appears on one of the labels. If a shipment does not conform to the guidelines above, it should be returned to the MRI center for correction.

If these procedures are followed, there should be no reason that the Reading Center would receive incomplete shipments. If, however, anything is missing from a shipment, the Reading Center will contact the MRI center directly and cc the Coordinating Center.

Requests for repeat scans, in the event that the initial scan was not usable or is missing, will be sent directly to the QC person at the Field Center. While it is desirable to get usable scans on all eligible participants, we realize that practical considerations may make it undesirable to ask some participants to come back for a repeat MRI. Therefore, it will be left up to the clinical and professional judgment of the QC person to decide whether to re-contact the participant. If a participant will not be re-contacted or is contacted and refuses to undergo a repeat MRI, you must notify the Reading Center, so that this can be noted in the database comments field and a repeat request will not be sent.

Send the shipment to:

HABC C/O Jing Li OARG Quality Assurance Center University of California, San Francisco 350 Parnassus Avenue, Suite 800 San Francisco, CA 94117-1349

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For each shipment, complete the knee MRI Shipment Notification form, and fax a copy to the OARG at UCSF (Appendix 4).

Complete the form by filling in:

- MRI site identification
- Date of shipment and expected delivery date
- Courier and airway bill # (remember to keep your copy of the Airway bill).
- Range of exam dates included in shipment (mm/dd/yy to mm/dd/yy)

4.0 Data Handling at UCSF

All image data will be sent on hard copies and DAT tapes or optical disks to UCSF for centralized analysis.

4.1 Quality Reading of Images

The images will be checked using the Knee MRI Logsheet (Appendix 3) to ensure that all sequences in the protocol were included and that the pulse parameters used were in agreement with the protocol. The images will also be checked for adequate anatomical coverage, signal-to-noise ratio, and the presence of artifacts.

Confirmation that the image data was received will be faxed to the clinical site within 3 working days of receipt of the images to allow a repeat examination to be performed within 1 week of the original examination, if necessary.

If problems with image quality or protocol adherence are encountered, UCSF will interact directly with the study center to correct the problem.

5.0 Questions regarding the techniques outlined in this manual should be directed to

Yves Miaux, MD, MSc

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Questions regarding data management should be directed to:

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APPENDIX 1 Pre-visit Screener for Knee X-ray

	Health ABC	HABC Enrollment ID #	Acrostic Date Forr	n Completed Staff ID #
			Month E	Day Year
		E-VISIT SCREEN		
	Script: These questions This includes the front,	s are about pain, aching or stil back and sides of the knee.	ffness i <u>n, or around,</u> your l	mees.
0	In the past 12 months	s, have you had any <u>pain, ach</u>	ing, or stiffness in either kr	nee?
	Yes	No	Don't know	Refused
		Schedule a Year 2 follow-up vi	sit.	
2	In the past 30 days, h (Interviewer Note: "	ave you had <u>pain, aching or s</u> On most days" refers to 15	tiffness in either knee on or more days out of 30 d	most days? ays.)
	Yes	No No	Don't know	Refused
	Schedule a Year 2 follow-up visit WITH knee x-ray. Go to Question #4.			
<u></u>	In the past 12 months (Interviewer Note: "	, have you had <u>pain, aching o</u> On most days" refers to 15 o	r stiffness, in either knee o or more days out of 30 d	on most days for at least a month?
	Yes	₩	Don't know	Refused
	Schedule a Year 2 follow-up visit WITH knee x-ray. Go to Question #4.	Schedule a Year 2 follow-up visit with NO knee x-ray. STOP.		
4	Has a knee x-ray beer	scheduled?		
	Yes	No		
	When? Month Day	/ Year		
				29997
			Ve	rsion 1.0, 6/17/98

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APPENDIX 2 Knee MRI Eligibility and Tracking (page 1 of 2)

		(Pug(. I UI ~,	
	Health ABC		HABC Enrollm	eent ID # Acrostic Staff ID #
	KN	EE MRI ELIGII	BILITY AN	ND TRACKING
0	Reason for MRI exam:	Knee symptoms	Rando	om sample
2	Does participant weigh > 2 (Examiner Note: Do not page 7, question #1.)	!50 lbs (>113.5 kg)? re-weigh participant. Ch	eck weight mea	surement in Year 2 Clinic Visit Workbook,
	Yes	No		
		p circumference. If maxim 160 cm, do not test.	ıum	
8	(Examiner Note: Ask par Do you have a heart pacen		ions.)	
	Yes	☐ No	Don't know	Refused
	Do not test.	Do not	t test.	Do not test.
_	Here you are bed a server			
4	Have you <u>ever</u> had a surge	ry to repair an aneurysm?	Don't know	□ Potinod
			J DON'T KNOW	Refused
	Do not test.	Do no	t test.	Do not test.
0	Have you <u>ever</u> worked in a	machine shop where sma	Il metal slivers m	ay have entered your eye?
	Yes	∏No □	Don't know	Refused
	-		<u>-</u>	 _
	Do not test.	Do no	t test.	Do not test.
(Have you ever had an injury	in which metal or metal fr	ragments may ha	ave entered your eye?
	Yes	□ No □	Don't know	Refused
	Do not test.	Do no	t test	Do not test.
0	Have you had any surgery i	n the past two months?		
	Yes	□No □	Don't know	Refused
	Test can be scheduled	Test can b	e scheduled	Test can be scheduled
	after 2 months have passed since surgery.	after 2 mo	nths have nce surgery.	after 2 months have passed since surgery.
	3.7	,	va.gory.	passed sinds sanguly.
(3)	Have you ever had any surg		our heart?	
	Yes	□ No □	Don't know	Refused
	Do not test.	Do no	t test.	Do not test. 21812
]		21812
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APPENDIX 2

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		(page & or &)	- 10: 10: 00: 00: 00: 00: 00: 00: 00: 00:
	Health ABC KNEE MI	RI ELIGIBILITY AN	ID TRACKING
0	Have you had a hearing device surgically Yes No Do not test.	EE MRI ELIGIBILITY AND TRACKING e surgically implanted in your ear (not a regular hearing aid)? No Don't know Refused Do not test. accement in either knee? No Don't know Refused de claustrophobia is a firm contraindication. True claustrophobia is relatively and with claustrophobia will know who they are. Some may say they are es, but may tolerate MRI without difficulty. It is useful to make an attempt in or who have mild concern.) No Don't know Refused It is willing to try the test. FSE No Reason: sed T2-weighted FSE No Reason: sed FSE No Reason: FSE No Reason: GRESSON: REASON: BEAD NO REASON: B	
•	Have you had a total knee replacement in Yes No		Refused
•	uncomfortable in small spaces, but ma persons who seem uncertain or who h	claustrophobia will know who to any tolerate MRI without difficultiave mild concern.) Don't know	they are. Some may say they are ty. It is useful to make an attempt in
P	Was MRI performed for? Right knee a. Axial T2-weighted FSE Yes b. Sagittal fat suppressed T2-w Yes C. Coronal T2-weighted FSE	eighted FSE	Reason:
	Left knee a. Axial T2-weighted FSE Yes b. Sagittal fat suppressed T2-weighted FSE Yes c. Coronal T2-weighted FSE	☐ No ———————————————————————————————————	Reason:
18	Facility a. Memphis Baptist Memphis Park Ave Memphis LeBonher Pittsburgh UPMC		The state of the s
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APPENDIX 3 Knee MRI Log Sheet (page 1 of 2)

HABC Enrollme	nt ID # Acrostic Date of MRI Clinical Site	
O BE COMPLETED AT	KNEE MRI LOG SHEET	
Is package complete for this		
Comments		
Date shipped to OARG:	Month Day Year MRI Coordinator ID #:	
BE COMPLETED BY	UCSF QA CENTER	-
Date Received:	Month Day Year	
Is it complete?	Yes No	
	What is missing or incorrect? Film Tape	
	Sequence Image	
	Logsheet Other	
Received and check	ked by:	
A CENTER DATA PRO	DCESSING	
Data Receipt Acknowledged:	Month Day Year	
Internal Quality Control:	Month Day Year	
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APPENDIX 3

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KNEE MRI LOG SHEET

		Field Center QA			UCSF QA				
		Left Right			Left	j j	Right		
Exam N	√umber:		- AL						
Film ma	agnification factor:	☐ None	1.2	☐ None	Ш				
		Note: If "not OK" specify reasons below in comments section (include number, eg., 1, 2, 3, or 4)				Note: If "not OK" specify reasons below in comments section (include number, eg., 1, 2, 3, or 4)			
	Axial FSE T2 localizer	□ок	not OK	□ок	not OK	□ок	not OK	□ок	not OK
77	Sagittal FSE T2 w/fat suppression	□ок	not OK	□ок	not OK	□ок	not OK	□ок	not OK
•	Coronal FSE T2 DAT tape/optical	□ок	not OK	□ок	not OK	□ок	not OK	□ок	not OK
4	#	□ок	not OK	□ок	not OK	□ок	not OK	□ок	not OK
•	Quality Assurance	Exam QA MRI Tec	on site done	by:		UCSF Q			
Comments (Please note: include reasons for "not OK" checks here and specify changes in the protocol: for example, change in the frequency encoding axis. Include the number: eg., 1, 2, 3, or 4)						Accuracy Artifacts: Window I Other:		Accuracy Artifacts: Window L Other:	of sequence:

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APPENDIX 4 HEALTH ABC KNEE MRI SHIPMENT NOTIFICATION

TO: FAX:	Jing Li, OARG-UCSF (415) 502-5224	
FROM: SITE ID:	☐ Baptist (Memphis) ☐ LeBonheur (Memphis) ☐ Park Avenue (Memphis) ☐ Pittsburgh	
FAX: RE:	MRI Shipment of Health ABC Participant Data	
	Message	
The follo	wing data is being sent to you today(today's date)	
For deliv	ery on	
VIA: M	ail Delivery service: Airbill #	(airbill number)
Exam Da	te Range of Participants Included:	Year
Please ca	ll at if you hav if you hav	e any questions
•	e from OARG: nent received on: Month Day Year	
□ Not re	eceived as of: Month Day Year	

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Comments:				
	_	<u> </u>		

APPENDIX 5 Selection of MRI Controls

We would like to obtain MRIs on an additional 500 Health ABC participants without knee symptoms. The goal is to recruit one willing participant without knee symptoms per day, on average, for an MRI control group, or 5 per week, at each field center.

To recruit participants for the MRI control group observe the following protocol:

- Attempt to recruit the first <u>asymptomatic</u> participant identified, based on answers to the "symptoms" questions, each day. Please refer to the Year 2 Clinic Visit Workbook, page 35-36, questions #1-4.
- If the participant agrees to undergo an MRI, administer the Knee MRI Eligibility and Tracking Form (Year 2 Clinic Visit Workbook, page 44) to identify exclusions.
- If the first eligible participant refuses or is excluded based on the Knee MRI Eligibility and Tracking Form, attempt to recruit the second eligible participant, and so on.
- If no eligible persons are successfully recruited on a given day, attempt to recruit two participants to the MRI control group the following day, and so on, so that the goal of recruiting five participants per week is attained.
- Each calendar week will be designated for the recruitment of a specific race/gender group. For example, week 1 will be focused on recruitment of black women, week 2 white women, etc. Calendars will be provided that list the designated race and gender for each week.
- If 5 persons of the designated race/gender group are not recruited in a given week, the remaining quota for that group should be carried over into the following week. For example, if only 3 black women are successfully recruited in week 1, then attempt to recruit 2 additional black women in week 2. This will be in addition to the 5 white men that are to be recruited in week 2.
- Replacement of no-shows/cancellations: If a recruited person drops out of the control group by failing to show for an MRI scan and is not rescheduled, immediately attempt to recruit another person of that race/gender group regardless of the week.
- We encourage you to keep track of daily and weekly recruitment quotas and results by posting the calendars on a bulletin board accessible to all staff. Please indicate on these calendars the successful recruitment of an MRI control by marking an "X"

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in the appropriate box. At the end of each month, please fax these calendars to Susan Rubin (fax: 415/597-9213).

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MRI CONTROL GROUP

Sep	tember					
Sun	Mon	Tue	Wed	Thu	Fri	Sat
		, 1	2	3	4 □ <i>BF</i>	5
6	7 Holiday	8 □ <i>BF</i>	9 □ <i>BF</i>	10 □ <i>BF</i>	11 □ <i>BF</i>	12
13	14 □ <i>WF</i>	15 □ <i>WF</i>	16 □ <i>WF</i>	17 □ <i>WF</i>	18 □WF	19
20	21 □ <i>BM</i>	22 □ <i>BM</i>	23 □ <i>BM</i>	24 □ <i>BM</i>	25 □ <i>BM</i>	26
27	28 □ <i>w</i> M	29 □ <i>wM</i>	30 □ <i>wM</i>			
						998

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